INTERIM SAMPLING METHOD FOR THE DUODENOSCOPE – DISTAL END AND INSTRUMENT CHANNEL

CDC Disclaimer: This protocol has not been validated. The protocol is still being developed and evaluated for the major duodenoscope types; however, a version of this protocol has been used with Olympus, small intestinal videoscopes, models TJF-160VF and TJF-Q180V. This is an interim protocol and will be updated accordingly.

Purpose

This method is for use in the field to sample reprocessed duodenoscopes (after drying) for bacteria specifically located on the distal end; and for collecting samples from the instrument channel (via the instrument port to the distal end). Ideally, two personnel should perform this protocol, where one will hold the duodenoscope (**facilitator**) and the other person samples (**sampler**) accordingly. It is important to sample gently, while thoroughly, in order for optimal sampling and maintaining the integrity of the duodenoscope.

Materials and Reagents

- Sterile channel-opening brush, specific to the duodenoscope model manufacturer recommendations (one example - Olympus, #MH-507)
    - Note: Facility may choose to use the non-sterile disposable channel-opening brush but interpretations of positive cultures may be difficult
- Sterile 0.01M phosphate buffered saline (PBS) with 0.02% Tween®-80 solution (PBST) (one example - Teknova, #P3875)
- Sterile leak-proof specimen cups (120 mL) (one example - Fisher Scientific, #14-375-462)
- Sterile irrigation water (50 mL per duodenoscope)
- Sterile 60-cc syringes
- Additional materials:

	Parafilm®	Sterile alcohol pads	Hair coverings
	Sterile gloves	Permanent marker	Sterile gowns
	Sterile diaper pads	Face masks/ shields	Tray with sterile liner
	Labels		

Definitions

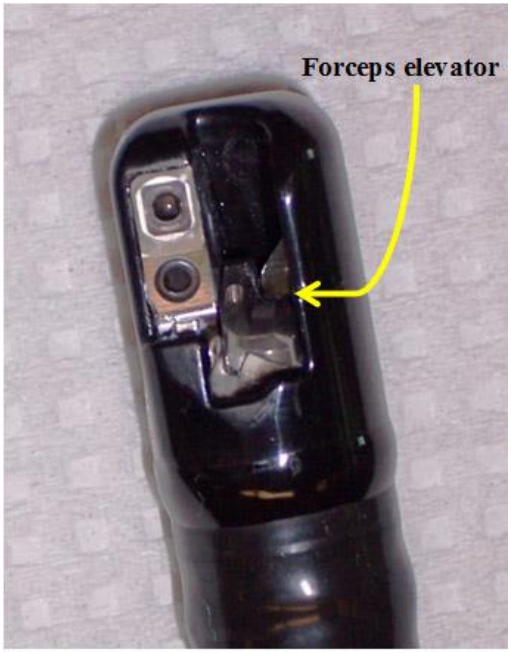
Distal end – Includes the elevator mechanism (e.g. forceps elevator or elevator) and elevator recess for duodenoscopes with sealed elevator wire channel; and elevator mechanism, elevator recess, and elevator channel for duodenoscopes with unsealed elevator wire channel.

Lowered/ closed position - Notes the position of the elevator mechanism being parallel or within the elevator recess relative to the distal end of the duodenoscope, Figure 1a.

Raised/ open position - Notes the position of the elevator mechanism being perpendicular to the distal end of the duodenoscope, Figure 1b.

Figure 1. Distal end, Model TJF-Q180V (Olympus) – Illustrating the orientation of forceps elevator in the (a) 'lowered/ closed' position and (b) 'raised/ opened' position (photos taken by CDC DHQP).

(a) Lowered/ closed forceps elevator



(b) Raised/ open forceps elevator

Method – Preparation of Materials

In Laboratory: Aseptically prepare specimen containers with PBST and sterile irrigation water if these reagents are not commercially available or already prepared

1.) Prepare autoclavable channel-opening brushes: Gather and wrap one channel-opening cleaning brush for use on each duodenoscope in appropriately-sized autoclave pouches; autoclave using approved sterilization cycles available in healthcare laboratories (132°C for 4 minutes or 135°C at 3 minutes)
2.) In a biological safety cabinet, aseptically prepare the following:
    a. Fill sterile leak-proof specimen containers with 50 mL PBST; label for brush samples with sample ID/ date
    b. Sterile irrigation water: aliquot 50 mL into sterile leak proof specimen containers; label for instrument channel flush with sample ID/ date
3.) Repeat step (2) for the total number of duodenoscopes to be sampled
4.) Save the remainder of stock PBST and irrigation water as negative controls

In the area where the duodenoscope(s) will be sampled:

1.) Clean and disinfect the counter where sampling of the duodenoscope(s) will be performed with an EPA approved disinfectant for hard, non-porous surfaces observing manufacturer's instructions on contact time and disinfection procedure
2.) **Sampler and Facilitator**: Don sterile gowns, face masks/shields, hair coverings and gloves
3.) Prepare the sampling materials by laying out the sterile diaper pad; placing respectively labeled sampling containers, pre-moistening PBST tubes in a rack, as well as other needed items (e.g. 60-cc syringes)
4.) Gather sterile cleaning and channel-opening brushes for sampling of the duodenoscopes

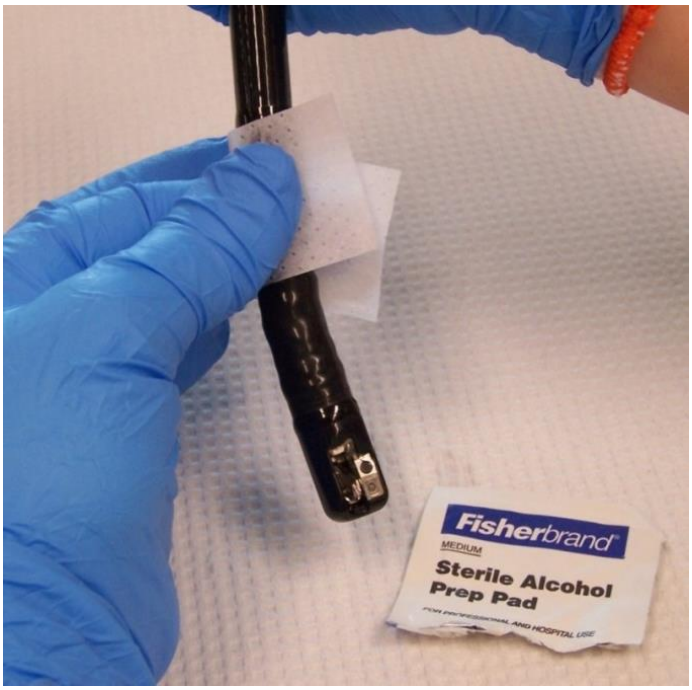
Method – Elevator mechanism and channel

1.) **Sampler and Facilitator**: Don sterile gloves
2.) **Facilitator**: Sanitize the outer surface of the duodenoscope tip with a sterile alcohol pad, but use caution to not wipe the elevator mechanism and lens face at the distal end that will be sampled with the channel-opening brush (Figure 2); allow to air dry prior to sampling. Place duodenoscope in tray with sterile liner until sampling
3.) **Facilitator**: Obtain the channel-opening brush and open the pouch for sampler to access brush
4.) **Facilitator**: Using the controller, set the elevator mechanism in the lowered/ closed position (Figure 1a) and orient the distal end (relative to the **Sampler**) for optimal sampling
5.) **Sampler**: Dip the channel-opening brush into the labeled PBST specimen container to pre-moisten the brush and press excess fluid from the brush inside the inner walls of the container

6.) **Sampler**: Using the pre-moistened channel-opening brush, with twisting motion of the brush, sample the inside of the elevator mechanism, recess, and channel in the lowered/ closed position (Figure 3a)

7.) **Facilitator**: Using the controller, set the elevator mechanism in the raised/ open position (Figure 1b) and then orient the distal end (relative to the **Sampler**) for optimal sampling inside the mouth of the specimen container

Figure 2. Clean the outer surface of the duodenoscope tip with a sterile alcohol pad but take care to not wipe the elevator mechanism and lens face (photo taken by CDC DHQP).

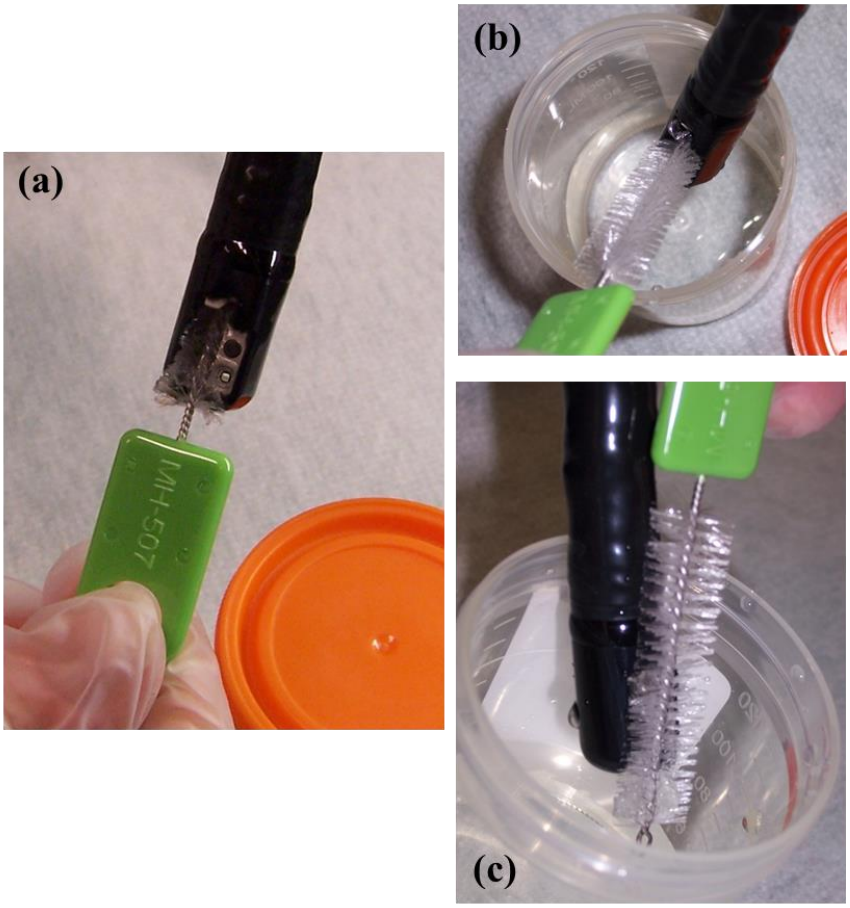


8.) **Sampler**: Using the channel-opening brush, firmly brush under the elevator mechanism in the raised/ open position (Figure 3b) and scrub the face of the lens (Figure 3c)

9.) **Sampler**: Drop the channel-opening brush portion inside the mouth of the corresponding labeled (*i.e.* sample ID, date) specimen container.

10.) **Facilitator**: Tighten the lid, and secure with Parafilm®

Figure 3. Sampling the elevator mechanism in the (a) 'lowered/ closed' position, (b) 'raised/ opened' position, and (c) sampling the elevator mechanism and lens face (photos taken by CDC DHQP).



Method – Instrument Channel

1.) **Sampler and Facilitator**: Replace and don sterile gloves if needed
2.) **Facilitator**: Obtain a sterile 60-cc syringe for the instrument channel sample, fill syringe with 50 mL sterile irrigation water from pre-filled and labeled specimen container, and hand to the **Sampler**
3.) **Facilitator** and **Sampler**: Coordinate how to hold the duodenoscope at the optimal angle for the **Sampler** to flush the instrument channel via the instrument port and the **Facilitator** to collect the sample in the specimen container

4.) **Sampler**: Flush the instrument channel with 50 mL of sterile irrigation water, specifically from the biopsy valve to the distal end to collect sample in sterile, labelled specimen container
5.) **Sampler**: Remove the 60-cc syringe and fill with air, then re-attach it to the instrument port and flush the air through the channel to flush out any remaining fluid into the sterile specimen container
6.) **Facilitator**: Tighten the lid, and secure with Parafilm®

Storage and Shipping Considerations

1.) Samples should be placed at 4ºC or on cold-paks for storage until further processing or shipping. Samples should not be stored beyond 24 hours after sampling
2.) Save and send remainder of unused irrigation water and PBST for testing (negative controls)
3.) When packaging for overnight shipping:
- Seal lids with Parafilm®;
- Place each specimen container in its own ziplock bag;
- Remainder of unused stock PBST and sterile irrigation water (negative control) in their own ziplock bags;
- All bags with tubes may be placed in several large outer bags

Duodenoscope handling after sampling

After sampling is complete, we recommend reprocessing the duodenoscope according to manufacturer's specifications while holding the scope until the microbial results are available.

Limitations

Environmental sampling and processing methods are to be used for investigational or research purposes. The sampling efficiency of this method has not been established.